

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-179

APPROVAL LETTER

1-1

NDA 21-179

JUL 12 2000

GelTex Pharmaceuticals, Inc.
Attention: Ms. Martha Carter
Vice President, Regulatory Affairs
153 Second Avenue
Waltham, MA 02451

Dear Ms. Carter:

Please refer to your new drug application (NDA) dated September 15, 1999, received September 16, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Renagel (sevelamer hydrochloride) Tablets, 400 mg and 800 mg.

We acknowledge receipt of your submissions dated October 14, November 15, and December 16, 1999, and March 30, May 23, June 12, 14, 16, and 19, and July 10, 2000.

This new drug application provides for a new dosage form of Renagel; i.e. tablets, in two strengths, 400 mg and 800 mg, for the reduction of serum phosphorus in patients with end-stage renal disease (ESRD).

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and immediate container and carton labels submitted July 10, 2000). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternately, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-179." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55; however on November 15, 1999, you submitted a pediatric drug development plan. We are deferring any decision on your pediatric drug development requirements until March 31, 2001, when your pilot study has been completed, and we have reviewed it.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug products when available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

[/S/]

John K. Jenkins, M.D.

Acting Director

Division of Metabolic and Endocrine Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

**APPEARS THIS WAY
ON ORIGINAL**

[/S/] 7/12/00

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cc:

Archival NDA 21-179

HFD-510/Div. Files

HFD-510/R.Hedin

HFD-510/Reviewers and Team Leaders

HF-2/MedWatch (with labeling)

HFD-002/ORM (with labeling)

HFD-102/ADRA (with labeling)

HFD-102/Post-Marketing PM

HFD-104/Peds/V.Kao (with labeling)

HFD-104/Peds/T.Crescenzi (with labeling)

HFD-42/DDMAC (with labeling)

HFI-20/Press Office (with labeling)

HFD-400/OPDRA (with labeling)

HFD-613/OGD (with labeling)

HFD-095/DDMS-IMT (with labeling)

HFD-820/DNDC Division Director

DISTRICT OFFICE

**APPEARS THIS WAY
ON ORIGINAL**

Drafted by: RH/June 29, 2000

Initialed by: EGalliers/6.29 & 7.12/BSchneider/RSteigerwalt/MHaber/DWu/RShore/
HAhn/1.11/EColman/7.12.00

final: RHedin 7.12.00

filename: N21179AP_Lt1.doc

APPROVAL (AP)